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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/804,408	FANRONG ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13 and 18, drawn to methods for typing a group B streptococcus by analyzing a gene selected from cpsD, cpsE, cpsF, cpsG and cpsI/M, classified in Class 435, subclass 6.

II. Claims 14-17 and 23, drawn to methods for typing a group B streptococcus by detecting a gene selected from rib, alp2 and alp3, classified in Class 435, subclass 6.

III. Claim 19-22, drawn to methods for typing a group B Streptococcus by detecting a gene selected from IS861, IS1548, IS1381, ISSa4 and GBSi1, classified in Class 435, subclass 6.

IV. Claims 24-27, 32 and 33, drawn to nucleic acids comprising a region within a cpsD-cpsE, cpsF-cpsG gene cluster, classified in Class 536, subclass 23.1.

V. Claims 28, 29, 32 and 33, drawn to nucleic acids comprising a region within a cpsI/M gene, classified in Class 536, subclass 23.1.

VI. Claims 30-33, drawn to nucleic acids comprising a region within a gene selected from the group of rib, alp2 and alp3 , classified in Class 536, subclass 23.1.

VII. Claim 34 and 35, drawn to nucleic acids comprising a region within a gene selected from IS861, IS1548, IS1381, ISSa4 and GBSi1, classified in Class 536, subclass 23.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are drawn to patentably distinct methods requiring the use of different reagents and having different effects and outcomes. The methods of invention I require the use of reagents for detecting nucleic acids of the genes cpsD, cpsE, cpsF,

cpsG and cpsI/M in order to accomplish the objective of detecting a genetic variation in the nucleic acid sequence of cpsD, cpsE, cpsF, cpsG or cpsI/M. The methods of invention II require the use of reagents for detecting a rib, alp2 or alp3 nucleic acid sequence in order to accomplish the objective of detecting a surface protein gene. The methods of invention III require the use of reagents for detecting IS861, IS1548, IS1381, ISSa4 or GBSi1 nucleic acid sequences in order to accomplish the objective of detecting a mobile genetic element. As each of the nucleic acids required to perform the methods of invention I, II, and III differ from one another with respect to their nucleotide sequence and their biological activity and effect, the methods for detecting nucleotide variations in these nucleic acids are considered to be patentably distinct from one another.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the nucleic acids of invention IV can be used in a materially different process, such as for synthesizing nucleic acids or proteins.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of

using that product (M.P.E.P. 806.05(h)). In the instant case, the nucleic acids of invention V can be used in a materially different process, such as for synthesizing nucleic acids or proteins.

Inventions I and VI and I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the nucleic acids of inventions VI and VII are not required to practice the methods of invention I.

Inventions II and IV, II and V, and II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the nucleic acids of invention IV, V, and VII are not required to practice the methods of invention II.

Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the nucleic acids of invention VI can be used in a materially different process, such as for synthesizing nucleic acids or proteins.

Inventions III and IV, III and V and III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and

they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the nucleic acids of invention IV, V, and VI are not required to practice the methods of invention III.

Inventions III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the nucleic acids of invention VII can be used in a materially different process, such as for synthesizing nucleic acids or proteins.

Further, should Applicants elect invention I, IV or V, these groups are subject to an additional restriction requirement as follows.

3. With respect to invention I, claims 2-4, 12, 13 and 18 are subject to an additional restriction since these claims are not considered to recite a proper genus/Markush group.

With respect to invention IV, claims 25-27, 32 and 33 are subject to an additional restriction since these claims are not considered to recite a proper genus/Markush group.

With respect to invention V, claims 29, 32 and 33 are subject to an additional restriction since these claims are not considered to recite a proper genus/Markush group.

Specifically, the above stated claims are drawn to genes and methods of using genes selected from the group consisting of cpsD, cpsE, cpsF, cpsG and cpsI/M. Additionally, the claims require particular nucleotide variations within these gene sequences at positions set forth in claims 2-4, 25-27. Claims 12, 13 and 29 also require patentably distinct primers selected from the group of primers set forth in Table 2. Claim 18 also requires the analysis of a second gene selected from the group of genes of rib, alp2 and alp3. Each of the genes, each of the nucleotide variations in the genes and each of the primers consist of different nucleotide sequences and have different biological functions and effects. Given the differences in structure and function, the Markush group set forth in these claims is not considered to constitute a proper genus, and therefore is subject to a further restriction requirement. A sequence search and non-patent literature search of these sequences would not be co-extensive with one another. For example, a search for the nucleic acid sequence of the cpsD gene would not be coextensive with a search of the nucleic acid sequence of the cpsE gene. Similarly, a search for a nucleotide variation at position 62 would not be co-extensive with a search for a nucleotide variation at position 78-86. Additionally, a search for the individual primers set forth in Table 2 would not be coextensive with one another. Further, a reference which renders obvious or non-novel the nucleic acid of the cpsD gene, for example, would not also necessarily render obvious or non-novel the nucleic acid of the cpsE gene. Similarly, a finding that the nucleic acid of the CpsD gene is novel and unobvious over the prior art would not necessarily extend to a finding that nucleic acid of the CpsE gene is also novel and unobvious over the prior art.

Accordingly, a search of more than one of the genes, nucleotide variations and primers set forth in the claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and the corresponding examination of more than one of the claimed sequences. **Therefore, if Applicants elect invention I, IV or V, Applicants are required to elect one of the stated genes, a corresponding nucleotide variation or a particular combination of nucleotide variations, and a specific primer or set of primers selected from the primers of Table 2. If Applicants elect invention I, Applicants must also elect a single gene selected from the genes of rib, alp2 and alp3.**

With respect to the stated genes, each of the genes constitutes a distinct chemical compound and each has a distinct functional property. These genes are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

Regarding the nucleotide variations and the primers of Table 2:

With respect to invention I, claims 1, and 5-11 link the individual nucleotide variations and primers of claims 2-4, 12, 13 and 18, each of the nucleotide variations and primers comprising a distinct invention as outlined above.

With respect to invention IV, claim 24 links the individual nucleotide variations and primers of claims 25-27, 32 and 33, each of the nucleotide variations and primers comprising a distinct invention as outlined above.

With respect to invention V, claim 28 links the individual nucleotide variations and primers of claims 29, 32 and 33, each of the nucleotide variations and primers comprising a distinct invention as outlined above.

The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.0.

Further, should Applicants elect invention II or VI, these groups are subject to an additional restriction requirement as follows:

4. With respect to invention II, claims 17 and 23 are subject to an additional restriction since these claims are not considered to recite a proper genus/Markush group.

With respect to invention VI, claims 31-33 are subject to an additional restriction since these claims are not considered to recite a proper genus/Markush group.

Specifically, the above stated claims are drawn to genes and methods of using genes selected from the group consisting of rib, alp2 and alp3. Additionally, claims 17 and 31 also require patentably distinct primers selected from the group of primers set forth in Table 6. Claim 23 also requires the analysis of a second gene selected from the group of genes of IS861, IS1548, IS1381, ISSa4 and GBSi1. Each of the genes and each of the primers consist of different nucleotide sequences and have different biological functions and effects. Given the differences in structure and function, the Markush group set forth in these claims is not considered to constitute a proper genus, and therefore is subject to a further restriction requirement. A sequence search and non-patent literature search of these sequences would not be co-extensive with one another. For example, a search for the nucleic acid sequence of the rib gene would not be coextensive with a search of the nucleic acid sequence of the alp2 or alp3 gene. Additionally, a search for the individual primers set forth in Table 6 would not be coextensive with one another. Further, a reference which renders obvious or non-novel the nucleic acid of the rib gene, for example, would not also necessarily render obvious or non-novel the nucleic acid of the alp2 or alp3 gene. Similarly, a finding that the nucleic acid of the rib gene is novel and unobvious over the prior art would not necessarily extend to a finding that nucleic acid of the alp2 or alp3 gene is also novel and unobvious over the prior art. Accordingly, a search of more than one of the genes and primers set forth in the claims presents an undue burden on the Patent and

Trademark Office due to the complex nature of the search and the corresponding examination of more than one of the claimed sequences. **Therefore, if Applicants elect invention II or VI, Applicants are required to elect one of the stated genes or a combination of said genes, and a corresponding primer or set of primers selected from the primers of Table 6. If Applicants elect invention II, Applicants must also elect a single gene selected from the genes of IS861, IS1548, IS1381, ISSa4 and GBSi1.**

With respect to the stated genes, each of the genes constitutes a distinct chemical compound and each has a distinct functional property. These genes are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

Regarding the primers of Table 6:

With respect to invention II, claims 14-16 link the individual primers of claim 17, each of the primers comprising a distinct invention as outlined above.

With respect to invention VI, claim 30 links the individual primers of claims 31-33 each of the primers comprising a distinct invention as outlined above.

The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s)

depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.0.

Further, should Applicants elect invention III or VII, these groups are subject to an additional restriction requirement as follows:

5. With respect to invention III, claim 22 is subject to an additional restriction since these claims are not considered to recite a proper genus/Markush group.

With respect to invention VII, claim 35 is subject to an additional restriction since these claims are not considered to recite a proper genus/Markush group.

Specifically, the above stated claims are drawn to genes and methods of using genes selected from the group consisting of IS861, IS1548, IS1381, ISSa4 and GBSi1. Additionally, claims 22 and 35 also require patentably distinct primers selected from the group of primers set forth in Table 10. Each of the genes and each of the primers consist of different nucleotide sequences and have different biological functions and effects. Given the differences in structure and function, the Markush group set forth in these claims is not considered to constitute a proper genus, and therefore is subject to a

further restriction requirement. A sequence search and non-patent literature search of these sequences would not be co-extensive with one another. For example, a search for the nucleic acid sequence of the IS861 gene would not be coextensive with a search of the nucleic acid sequence of the IS1548, IS1381, ISSa4 and GBSi1 genes. Additionally, a search for the individual primers set forth in Table 10 would not be coextensive with one another. Further, a reference which renders obvious or non-novel the nucleic acid of the IS861 gene, for example, would not also necessarily render obvious or non-novel the nucleic acid of the IS861, IS1548, IS1381, ISSa4 and GBSi1 genes. Similarly, a finding that the nucleic acid of the IS861 gene is novel and unobvious over the prior art would not necessarily extend to a finding that nucleic acid of IS861, IS1548, IS1381, ISSa4 and GBSi1.

gene are also novel and unobvious over the prior art. Accordingly, a search of more than one of the genes and primers set forth in the claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and the corresponding examination of more than one of the claimed sequences. **Therefore, if Applicants elect invention III or VII, Applicants are required to elect one of the stated genes or a combination of said genes, and a corresponding primer or set of primers selected from the primers of Table 10.**

With respect to the stated genes, each of the genes constitute a distinct chemical compound and each has a distinct functional property. These genes are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to

represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species.

Regarding the primers of Table 10:

With respect to invention III, claim 19-21 links the individual genes and primers of claim 22, each of the primers comprising a distinct invention as outlined above.

With respect to invention VII, claim 34 links the individual genes and primers of claim 34, each of the primers comprising a distinct invention as outlined above.

The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.0.

6. These inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized

divergent subject matter. Further, inventions I-VII require different searches that are not co-extensive. For instance, a literature and sequence search for the methods for detecting the nucleic acids of invention I is not co-extensive with a literature and sequence search for the methods of detecting the nucleic acids of inventions II-III. Further, the searches for the nucleic acids of inventions IV-VII is not co-extensive with a search for the methods of inventions I, II and III. Further, a finding that the nucleic acid of invention IV, for example, is anticipated or obvious over the prior art would not necessarily extend to a finding that the method of inventions I-III or the nucleic acids of inventions V-VII were also anticipated or obvious over the prior art. Similarly, a finding that the method of invention I is novel and unobvious over the prior art would not necessarily extend to a finding that the methods of invention II-III or the nucleic acids of inventions IV-VII are also novel and unobvious over the prior art. Accordingly, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
Art Unit 1634

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER